UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trad mark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
09/618,129	07/17/00	WANG	X	55861-00003

HM11/0920

JOSEPH H KIM
SQUIRE SANDERS & DEMPSEY LLP
801 S FIGUEROA STREET
14TH FLOOR
LOS ANGELES CA 90017-5554

EXAMINER	
SPIEGLER, A	
ART UNIT	PAPER NUMBER
1656	7

DATE MAILED: 09/20/01

Remail out

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trad mark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

10

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/618,129	07/17/00	WANG X	49657-754

HM12/0403

MCDERMOTT WILL & EMERY
600 13TH STREET NW
WASHINGTON DC 20005-3096

EXAMINER
SPIEGLER, A

ART UNIT	PAPER NUMBER
1656	4

DATE MAILED: 04/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/618,129	WANG, XIAO BING	
	Examiner	Art Unit	
	Alexander H. Spiegler	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 July 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities:

A) Page 9, recites "W represents a complementary...", but Figure 1 does not contain a "W".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. Claims 1-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 1-36 are indefinite over the recitation of "or optionally" because it is not clear as to whether the primer extension reagent comprises one type of terminator or absence of a nucleotide that is complementary to the target base at the predetermined position of the nucleic acid of interest and three types of non-terminator nucleotides.

B) Claims 16, 18, 20-22 are indefinite over the recitation of "allows" because it is not clear whether or not the primer actually does link to a solid surface.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claims 1-23, 27-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Soderlund (US 6,013,431).

Soderland teaches a method for detecting a target nucleic acid comprising: (a) providing a detectable amount of a target nucleic acid polymer in a single stranded form, (b) hybridizing the detectable amount of the nucleic acid polymer with one or more oligonucleotide primers (forming a primer-nucleic acid duplex), wherein each primer has a nucleotide sequence that is complementary to a sequence in the target nucleic acid polymer, such that when the primer is hybridized to the target nucleic acid polymer, the 3' end of the primer binds to a nucleotide flanking the specific nucleotide at the defined site in the target nucleic acid (i.e. the first unpaired base immediately downstream of the 3' end of the primer), (c) exposing the hybridized nucleic acid polymer to a polymerization agent in a mixture containing at least one deoxynucleotide, said deoxynucleotide comprising a detectable label, and one or more chain terminating nucleotide analogues, such that a detectable primer extension product is formed if the labeled deoxynucleotide is complementary to the specific nucleotide at the defined site, and (d) analyzing the polymerization mixture of step (c) for the presence or absence of the primer extension product containing the labeled deoxynucleotide at the 3' end thereof, whereby the identity of the specific nucleotide at the defined site is determined (col. 18, ln. 19-53).

The reference also teaches that two or more differently labeled dNTPs (non-terminator nucleotides) can be added to the primer-nucleic acid duplex, wherein the detection is better interpreted by adding dNTPs that are different than the terminator nucleotide (col. 8, ln. 58-64). The reference also teaches the use of this invention with various labels such as radioactive or fluorescent labels (see examples 1-7, col. 9-18). The reference also teaches that the primer

extension reaction can be performed by enzymatic means using template dependent enzymes (i.e. T7 DNA polymerase, T4 DNA polymerase, reverse transcriptase, etc.) (col. 8, ln. 10-17). The reference also teaches that the primer may contain an attachment moiety (i.e. biotin, antigens, etc.) (col. 6, ln. 16-31), that permits affinity separation of the from the unincorporated reagent and/or the nucleic acid of interest (col. 6, ln. 53 to col. 7, ln. 26), and furthermore, that a solid support may be used in the separation process (col. 6-7). The reference also teaches that the nucleic acid of interest can be any human, animal, plant, or microbe (col. 5, ln. 25-32).

5. Claims 1-6 and 9-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Goelet et al. (US 5,888,819).

Goelet teaches a method of determining the identity of a nucleotide base at a specific position in a nucleic acid of interest, which comprises: (a) treating a sample containing the nucleic acid of interest, if the nucleic acid is double-stranded, so as to obtain unpaired nucleotide bases spanning the specific position, or directly employing step (b) if the nucleic acid of interest is single-stranded; (b) contacting the sample from step (a), with an oligonucleotide primer which is fully complementary to and which hybridizes specifically to a stretch of nucleotide bases present in the nucleic acid of interest immediately adjacent to the nucleotide base to be identified, under high stringency hybridization conditions, so as to form a duplex between the primer and the nucleic acid of interest such that the nucleotide base to be identified is the first unpaired base in the template immediately downstream of the 3' end of the primer in said duplex; and (c) contacting the duplex from step (b), in the absence of dATP, dCTP, dGTP, or dTTP, with at least two different terminators of a nucleic acid template-dependent, primer extension reaction capable of specifically terminating the extension reaction in a manner strictly dependent upon the identity

of the unpaired nucleotide base in the template immediately downstream of the 3' end of the primer wherein one of said terminators is complementary to said nucleotide base to be identified and wherein at least one of said terminators is labeled with a detectable marker (and therefore, one terminator is unlabeled); wherein said contacting is under conditions sufficient to permit base pairing of said complementary terminator with the nucleotide base to be identified and occurrence of a template-dependent primer extension reaction sufficient to incorporate said complementary terminator onto the 3' end of the primer to thereby extend said 3' end of said primer by one terminator; (d) determining the presence and identity of the nucleotide base at the specific position in the nucleic acid of interest by detecting the detectable marker of said incorporated terminator while said terminator is incorporated at the 3' end of the extended primer, and wherein said detection is conducted in the absence of non-terminator nucleotides (col. 29, ln. 42 to col. 30, ln. 58).

The reference also teaches that the detectable markers may be a fluorophore, protein moiety, etc. (col. 8, ln. 52-59). The reference also teaches that primer extension reaction can be carried out using enzymatic means such as T4 DNA polymerase, T7 DNA polymerase, etc. (col.31, ln. 30-34). The reference also teaches that the primer comprises biotin which permits affinity separation of the primer from the unincorporated reagent and/or nucleic acid of interest via binding of the biotin to streptavidin which is attached to the solid support (col. 32). The reference also teaches the nucleic acid of interest may be synthesized enzymatically, synthesized by polymerase chain reaction, may comprise a non-natural nucleotide analog, genomic DNA from an organism, extragenomic DNA form an organism, wherein said organism is a virus,

mircoorganism, plant, vertebrate, invertebrate, mammal, or human being (col. 32, ln. 45 to col. 33, ln. 10).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (703) 305-0806. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Alexander H. Spiegler
April 2, 2001

Kenneth R. Horlick, Ph.D.
KENNETH R. HORLICK
PRIMARY EXAMINER
GROUP ~~1800~~ 1600

4/2/01